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September 25, 2008

Drug Enforcement Administration
8701 Morrisette Drive
Springfield, VA 22152
Attention: DEA Federal Register Representative/ODL

Subject: DEA Notice of Proposed Rulemaking: Electronic Prescriptions for Controlled Substances, 73 Fed. Reg. 125 (June 27, 2008) [Docket No. DEA-218P]

Dear Sir/Madam:

The Institute for Safe Medication Practices (ISMP) is a nonprofit organization recognized worldwide as an important educational resource for understanding and preventing medication errors. ISMP represents more than 30 years of experience in helping to keep patients safe through its efforts to improve the medication use process.

ISMP supports the DEA's intent to permit the electronic prescribing of controlled substances which currently represent 10-11% of all written prescriptions. The inability of physicians to e-prescribe controlled substances is considered a major barrier to the widespread adoption of e-prescribing technology. Computer to computer electronic prescribing has many benefits and efficiencies for the prescriber, pharmacy, and patient**.** Numerous studies show that e-prescribing is associated with reduced medication errors, the use of more cost-effective medications such as generics, improved patient compliance, and other savings and benefits across the health care spectrum. While this technology does not offer a perfect solution to prevent medication errors, ISMP does believe that if appropriately and aggressively used, it holds great promise for researching, identifying, reporting, and reducing medication errors.

ISMP applauds the DEA for supporting the adoption of electronic prescriptions for controlled substances in a manner that will eliminate the risk of diversion. While we believe this rule to be well-intended, we also believe that considerable changes are necessary to ensure the system works for pharmacies, providers, and patients. Barriers to adopting this new proposed rule in the pharmacy industry include, among others, costly and burdensome provisions in auditing requirements, record retention, validation of the prescriber's DEA number, and digital signature requirements. These proposed requirements have the potential to cause disturbances in workflow issues for providers thus prohibiting the widespread adoption of e-prescribing. These will inadvertently result in distractions to the prescription filling process which in turn could lead to further medication errors and less pharmacist consultation time with the patient.

Our concerns with the DEA new proposed rule for the electronic prescribing of controlled substances follows are outlined below.

We are concerned that DEA has proposed burdens upon practitioners and pharmacies for which we see no clear benefit to DEA. Similarly, we are concerned that DEA is proposing requirements for electronic prescriptions that do not correspond to requirements for paper prescriptions and do not seem to be related to an electronic prescribing need. Hence, we are concerned that DEA is proposing requirements that are not necessarily relevant to the creation and transmission of electronic prescriptions.

1) Pharmacy Issues

a) Audit Requirements

i) *Third-party Audits*- Section 1311.170 (f) of the proposed rule would require the pharmacy dispensing system to undergo a third party audit prior to accepting any electronic controlled substance prescriptions and to redo the audit annually thereafter. Undergoing these types of audits is not a common practice in the industry. Such an audit process is not currently required for paper prescriptions, including written prescriptions for controlled substances. We question the need for requiring such an annual audit merely because the pharmacy receives and maintains electronic prescriptions for controlled substances.

We believe this requirement is unnecessary as current polices and procedures are in place to comply with state statutory requirements, state board of pharmacy regulations, and the HIPAA privacy and security rules to adequately address privacy and security issues. Additionally, pharmacies are currently required to certify new releases of their systems with SureScripts-Rx Hub. We ask that DEA recognize the efforts that are currently in place to protect privacy and security. ISMP supports the position of the National Association of Chain Drug Stores (NACDS) in their proposal that DEA require that the pharmacy system be auditable by DEA or a DEA-named entity, rather than required to go through the costly and potentially unnecessary process of annual third-party audits.

ii) *Internal Audit Trail*- Section 1311.170(b) of the proposed rule would require the pharmacy system to create and maintain an internal audit trail that indicates each time a controlled substance prescription file is opened, annotated, altered, or deleted. The pharmacy system would have to identify each person who *views*, annotates, or alters the prescription record.

We question the need to require the audit trail to include every time a prescription is viewed. There are many steps in the prescription filling and verification process that ISMP would recommend the 'viewing' of the prescription by the pharmacy staff- as the prescription is entered into the pharmacy system, upon drug product selection, during verification of content and during verification of the mandated drug utilization review as well as during the final check and during patient consultation. This entire process is

repeated every time a prescription is refilled for a patient. Having to create and save an audit trail of every time every prescription is viewed for five years would require an enormous amount of electronic storage, and would be very costly and could have the unintended consequence of less viewing which would effect quality and accuracy rates, leading to errors.

iii) *Analyze Audit Trail and Report to DEA*- DEA is proposing to require the system to analyze the audit logs at least once every 24 hours and generate an incident report of events that could have compromised the integrity of the prescription records. *See* section 1311.170(d). A manual process would be tedious, unworkable within the 24 hour time frame, and may require additional personal thus increasing cost to pharmacy and take time away from safety initiatives, quality assurance checks and patient consultation. Even with an automated process, 24 hours may prove to be difficult to complete an audit.

In section 1311.170 (e), DEA proposes that any incidents of auditable events must be reported to the service provider and the DEA within one business day. Such a requirement may not be feasible considering increased workloads on busy days or after long weekends or holidays. ISMP would agree with the NACDS suggestion that a time period of forty-eight to seventy-two hours upon discovery would be reasonable and sufficient.

In addition to these and other concerns for pharmacy, it is imperative that this rule be workable for physicians, pharmacists and other affected individuals across the health care spectrum in order to increase the widespread adoption of e-prescribing. ISMP strongly supports the effort to increase the adoption of e-prescribing in order to improve the quality and efficiency of health care across the health care spectrum. We, like the DEA, recognize that the inability of physicians to electronically prescribe controlled substances is a major barrier to the widespread adoption of e-prescribing. We thank you for the opportunity to comment on this important issue that will serve to advance the widespread adoption of e-prescribing and thus reduce medication errors. If you have any questions, please feel free to contact us at ISMP.

Sincerely,

Michael R. Cohen, RPh, MS, ScD
President